K061335

510(k) Summary

Coastal Biocare
Enhance Dental Implant System

AUG - 9 2006

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Coastal Biocare 2737 South Croddy Way Unit D Santa Ana, CA 92704 Telephone (714) 751-0121 FAX (714) 751-0115
Official Contact:	Candy Pravitz
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Implant, Endosseous, Root-Form Abutment, Implant, Dental, Endosseous
Trade/Proprietary Name:	Enhance Dental Implant System
Common Name:	Dental implant, Dental Implant Abutments

DEVICE CLASSIFICATION

FDA has classified "Implant, Endosseous, Root-Form" as a Class II device (21 CFR 872.3640), with product code DZE. "Abutment, Implant, Dental, Endosseous" has a product code of NHA and is classified as Class II (872.3630). Endosseous dental implants and abutments are reviewed by the Dental Products Panel.

INTENDED USE

The Enhance Dental Implant System is intended to be surgically placed in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. It may be placed immediately in an extraction site or may be placed after bone healing.

DEVICE DESCRIPTION

The Enhance Dental Implant System (Enhance System) is a system of threaded root-form dental implants and abutments.

Design

Implants of the Enhance System are threaded endosseous dental implants with a finely grooved tapered collar. The implants are made of commercially pure titanium and are offered in a variety of lengths and diameters. Implants are configured with an internal hex to aid in surgical insertion and to prevent rotation of restorations. The Enhance System includes straight abutments of several types, cover (healing) screws and a retainer screw used to secure hex-configured abutments in place. Enhance System implants are individually packaged in a carrier vial that is sealed within a radiation-sterilizable Tyvek pouch. The other Enhance System components are provided non-sterile and are packaged in Tyvek pouches.

Material

Enhance System implants are made of CP titanium Grade 4, conforming to ASTM F 67 with abutments of Ti-6Al-4V ELI alloy conforming to ASTM F136.

Sterilization

Sterilization will be accomplished by means of Co^{60} gamma irradiation at a nominal dose of 25 kGy (2.5 Mrad).

EQUIVALENCE TO MARKETED DEVICE

Coastal Biocare demonstrated that, for the purposes of FDA's regulation of medical devices, the Enhance Dental Implant System is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

The intended use, design, materials and functional characteristics of the Enhance Dental Implant System and the predicate devices are substantially the same. All are indicated for use in the bone of the maxillary and/or mandibular arch and are made of CP titanium and Ti-6Al-4V ELI titanium alloy, well-proven materials for implantable devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2006

Coastal Biocare
C/O Mr. Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K061335
Trade/Device Name: Enhance Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: August 4, 2006
Received: August 7, 2006

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

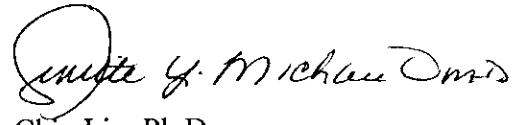
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K061335

Device Name:

Enhance Dental Implant System

Indications for Use:

The Enhance Dental Implant System is intended to be surgically placed in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. It may be placed immediately in an extraction site or may be placed after bone healing.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...) Number: K061335